REMARKS/ARGUMENTS

This document responds to the office action mailed on August 19, 2010. In that office action, claims 1-3 and 5-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,549,672 to Maddock et al. (hereinafter "Maddock") in view of U.S. Patent No. 4,650,464 to Ruiz, et al (hereinafter "Ruiz") and further in view of U.S. Patent No. 4,670,007 to Wheeldon et al. (hereinafter Wheeldon). Claim 4 was rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Maddock in view of Ruiz, Wheeldon, and further in view of U.S. Patent No. 6,319,221 to Savage et al. (hereinafter "Savage"). Reconsideration of these rejections, as they might apply to the original and amended claims in view of these remarks, is respectfully requested.

Once again, however, the cited references (a) fail to teach elements of the claimed embodiments and (b) teach away from the claimed embodiments.

Examiner's Interview

The undersigned and Mark E. Schafer, Ph.D., Chief Technology Officer of Sound Surgical Technologies LLC (assignee of the present application) thank Examiner Bouchelle for the in person interview conducted on December 9, 2010. A more detailed summary of the interview is being filed herewith.

Claim Rejections of Claims 1-3, 5-18 -- Under 35 U.S.C. § 103

Claims 1-3 and 5-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Maddock in view of Ruiz and Wheeldon. Applicant respectfully traverses this rejection because Maddock, Ruiz, and Wheeldon, alone and in combination, fail to teach all of the elements of the claims.

Although Applicant does not concede that the cited references teach all of the features of the currently pending claims, claim 1 is being amended herein to expedite allowance of subject matter and further distinguish from the cited references. Amended claim 1 recites, *inter alia:*

. . .

> a peristaltic pump for rapidly pumping the desired volume of the sterile fluid from the container to a targeted anatomical site or a device, the peristaltic pump having speed control adjustable by a user to deliver the sterile fluid at one or more rates selected by the user, the one or more rates being within the range of 30 ml/min to 1000 ml/min, wherein the desired volume ranges from 100 ml to 5000 ml;
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> a processor for processing the electrical output from the strain gauge to determine the volume of fluid delivered for the surgical procedure, wherein output from the processor is not electronically connected to the peristaltic pump to adjust the speed of the peristaltic pump during delivery of the sterile fluid, and wherein determination of the volume of fluid delivered is not affected by a change in the one or more rates during delivery of the sterile fluid
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Maddock, Ruiz, and Wheeldon fail to teach at least these features of claim 1.

As described in previous responses, Maddock discloses a system for filling mammary prostheses and tissue expanders. *See Maddock,* col. 2, lns. 40-41. The pumping system delivers flow at a desired flow rate or pressure through a tube to an injection needle used to fill the inflatable mammary prosthesis or the tissue expander. *See id.* col. 2, lns. 42-48. The pumping system may include fluid volume measuring capabilities. *See id.* Maddock teaches that "the volume of the inflation fluid pumped by the pump is directly proportional to the total rotation of the pump head." *Maddock*, col. 5, lns. 64-66. Accordingly, any change in flow rate will affect the determination of the volume that has been delivered. That is, a changed flow rate will be reflected in the rotation of the pump head and thus the determination of the delivered volume. As noted above, this is in contrast to claim 1, which provides for "wherein determination of the volume of fluid delivered is not affected by a change in the one or more rates during delivery of the sterile fluid."

Ruiz does not compensate for the deficiency in Maddock. Ruiz describes an apparatus for monitoring infusion of intravenous fluid into a patient. *See Ruiz,* col. 1, lns. 46-48. The monitoring is performed using a weight sensing transducer, which generates an analog signal that is transmitted to a computer after being converted to a digital signal. *See id.* at col. 2, lns. 32-41. Ruiz describes that the invention is designed so that "[t]he volume of fluid infused into a patient is determined in accordance with the present invention by disregarding large changes in weight (due to addition of fluid bags to rack 26 or due to jarring of rack 26), and calculating the fluid

infused only from weight data that decreases in approximately linear fashion." *Id.* at col. 2, , lns. 50-55.

Applicant first notes that Ruiz is directed to a device for intravenous delivery of fluids which is significantly slower than flow rates contemplated with embodiments of the present invention. Indeed, the apparatus of Ruiz delivers fluid to a patient over a very long period of time relative to the time for embodiments of the present invention. As noted by Ruiz, "The program is designed to take 100 data readings to make up one data sample every 30 seconds. A second array, dimensioned V(240), is used to acquire and store the data samples taken from each set of 100 data samples ***over a two hour period.***" *Id.* at col. 4, lns. 14-21. Accordingly, Applicants submit that a person of ordinary skill in the art would not look to the system of Ruiz, which provides for delivery of fluids over *two hours*, in creating a device for rapidly delivering fluids.

Furthermore, as noted above, an important feature of the Ruiz system is the ability to disregard large changes in volume delivered to a patient. Ruiz "disregard[s] large changes in weight (due to addition of fluid bags to rack 26 or due to jarring of rack 26), and calculate[es] the fluid infused only from weight data that decreases in approximately linear fashion." *Id.* at col. 2, lns. 50-55. Ruiz disregards large sudden changes in weight, because such changes are presumed to reflect some event outside the normal dripping/infusion of fluid. This important feature of Ruiz is inconsistent with the claimed embodiments of the present invention, which provides for rapid delivery of fluids, resulting in large changes over short periods of time. These large changes would be disregarded by the program described in Ruiz. In the system of Ruiz, if the delivery rate during delivery were changed for example to 1000 ml/min, Ruiz would disregard this change because this flow rate is faster than is possible with intravenous infusion. *See Ruiz* at col. 5, lns. 55-56. Furthermore, even if the rate were changed to a relatively slower rate, as Ruiz notes, "the fluid infused [is calculated] only from weight data that decreases in approximately linear fashion." Changing the rate of fluid delivery during delivery of the fluid creates non-linear changes in weight data. The changes in delivery rate would therefore have an effect on the determination of volume, i.e., they would likely be ignored in the volume calculation, which is contrary to the noted feature of claim 1. For at least this reason, Ruiz does not compensate for the deficiency in Maddock because it does not teach or suggest that a "determination of the

volume of fluid delivered is not affected by a change in the one or more rates during delivery of the sterile fluid," as recited in claim 1.

Applicant also submits that it would not be obvious to modify the device described by Maddock with features of the Ruiz device. As noted above, Ruiz relates to intravenous delivery of fluids that occur in time intervals of up to 2 hours. Such a time frame is inconsistent with an objective of the Maddock device, i.e., filling mammary prosthesis with the goal to reduce the amount of time it takes for fluid delivery to reduce the chance of infection. *See Maddock*, col. 2, lns. 32-36. A person of skill in the art would not look to devices like the Ruiz device to create an improved device for filling a mammary prosthesis because the delivery of fluid occurs at rates that would be counter productive to the goal of reducing the amount of time it takes to fill the prosthesis.

Additionally, the office action implies that it would be obvious to a person of ordinary skill in the art to modify the Maddock device with the processor disclosed in Ruiz, which, as alleged in the office action, is "used only to determine the volume of fluid delivered and is not coupled to any other components of the infusion system." *Office Action, 8/19/10*, p. 3. Applicant respectfully disagrees because Maddock has teachings that are inconsistent with this type of modification. Maddock specifically provides for having a programmable pump, "wherein the pump will automatically shut off after a given volume of fluid has been pumped, thereby providing a direct and accurate measure of the inflation fluid delivered through inflation tube 64 to the prosthesis." *Maddock*, col. 5, lns. 67-col. 6, ln.3. If the Maddock device were modified as suggested in the office action, namely with a processor that only determines the volume of fluid delivered and is not coupled to other components, the device would presumably not provide for automatically shutting off the pump when a particular volume was infused. Accordingly, the modifications suggested by the office action are directly contrary to the teachings of Maddock.

In addition to Maddock and Ruiz, the office action also cites to Wheeldon, which as noted in the office action is "only being relied upon to teach that a strain gauge is a known sensing transducer." *Office Action*, 8/19/10, p. 6. Wheeldon provides a fluid flow control process and apparatus that is designed to accurately dispense fluid, at a selected delivery rate, from a fluid container. *See Wheeldon*, col. 3, lns. 33-36. Wheeldon describes the use of a weight

sensing device that monitors the weight loss of a fluid container. *Id.* at col. 5, lns. 18-20. The weight sensing device is used to calculate the volume of fluid dispensed and the actual rate of delivery of fluid. *Id.* at col. 5, lns. 21-29. If the actual rate of delivery is different from the selected rate, the speed of the pump is adjusted to correspond to the selected rate. *Id.* at col. 3, lns. 50-63.

Applicant points out that the Wheeldon device "is particularly designed for controlling an intravenous infusion system utilizing a peristaltic pump and a standard administration set for delivery of fluid to a patient," and not for rapid delivery of fluids. *Wheeldon*, col. 4, lns. 20-23. As noted above, a person of ordinary skill in the art would not look to an intravenous delivery device such as Wheeldon's to modify a device for filling a mammary prosthesis as disclosed by Maddock. A goal of the Maddock device is to reduce the amount of time it takes for fluid delivery to the prosthesis to reduce the chance of infection. *See Maddock*, col. 2, lns. 32-36. The Wheeldon device with its intravenous flow rates would therefore not be useful for rapid delivery of fluids. For at least the reasons noted above, the combination of Maddock, Ruiz, and Wheeldon do not render claim 1 obvious.

Claim 1 further recites "a peristaltic pump for rapidly pumping the desired volume of the sterile fluid from the container to a targeted anatomical site or a device, the peristaltic pump having speed control adjustable by a user to deliver the sterile fluid at one or more rates selected by the user, the one or more rates being within the range of 30 ml/min to 1000 ml/min, wherein the desired volume ranges from 100 ml to 5000 ml." As noted in the office action, the Applicant has previously argued that Maddock did not teach at least the claimed rates neither explicitly nor inherently. The office action responds by stating that the use of Maddock is not an inherency rejection because the limitation "the pump having speed control adjustable by a user *for delivery of the sterile fluid at a rate . . .*" is considered to be an intended use limitation. *Office Action*, 8/19/10, p. 6 (emphasis in original). Applicants respectfully disagree.

Nevertheless, claim 1 has been amended to recite "the pump having speed control adjustable by a user ***to deliver*** the sterile fluid at one or more rates selected by the user. . . ," which is not an intended use limitation. The office action also alleges that since Maddux discloses a device for use in the same procedure as the claimed procedure it is therefore capable of performing the claimed function. *See Office Action*, 8/19/10, p. 6. However, as indicated in

the last response, the mere possibility that the pump disclosed in Maddock could operate at the claimed rates does not establish that those rates are used. "The examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112 (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). Maddock does not provide enough information to indicate that the disclosed pump necessarily operates within the claimed flow rate range.

Ruiz and Wheeldon are designed for intravenous fluid delivery and therefore fail to describe flow rates that are within the range recited in claim 1. For at least this additional reason, the combination of Maddock, Ruiz, and Wheeldon fail to teach all of the elements of claim 1, and therefore do not render claim 1 obvious. Claims 2-9 depend upon claim 1 and are allowable for at least the same reasons.

Independent claim 10 is directed to "a method for rapidly delivering and accurately monitoring the delivery of a desired volume of sterile fluid to a targeted anatomical site or a device." Claim 10 includes features similar to claim 1. Specifically, claim 10 recites:

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> connecting one end of a sterile tubing set to the container and connecting the tubing set to a peristaltic pump to create a flow path that passes through the peristaltic pump so that the peristaltic pump can remove the desired volume of the sterile fluid from the container at one or more rates selected by a user, the one or more rates being within the range of 30 ml/min to 1000 ml/min, wherein the desired volume ranges from 100 ml to 5000 ml;
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> processing with a processor the electronic signal from the strain gauge to display the volume of sterile fluid removed from the container, wherein output from the processor is not electronically connected to the peristaltic pump to adjust the speed of the peristaltic pump during delivery of the sterile fluid, and wherein determining the volume of sterile fluid removed from the container is not affected by a change in the one or more rates during delivery of the sterile fluid
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> . . .

As described in detail above, these features are not taught or suggested by the combination of Maddock, Ruiz, and Wheeldon. The cited references fail to teach all of the elements of claim 10. Claims 11 and 13-15 depend upon claim 10 and are allowable for at least the same reasons.

Claim Rejections of Claim 4 -- Under 35 U.S.C. § 103

Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock in view of Ruiz, Wheeldon, and further in view of Savage. Claim 4 depends upon independent claim 1 and includes all of the features recited in claim 1. Applicants traverse the rejection because the cited references do not teach all of the features of claim 4.

As noted in previous responses, Savage describes systems and methods of measuring fluid retention of a patient. *See Savage*, col. 2, ln 1. Savage teaches that the fluid retention or loss in a patient is determined by weighing fluid introduced into the patient to produce a fluid-in amount, weighing fluid collected from the patient to produce a fluid-out amount, and calculating a difference between the fluid-in amount and the fluid-out amount with the difference representing the fluid retention or loss of the patient. *See id*, col. 2, lns. 1-7. Savage does not compensate for the deficiencies in the other cited references. For example, Savage does not provide for "a peristaltic pump for rapidly pumping the desired volume of the sterile fluid from the container to a targeted anatomical site or a device, the peristaltic pump having speed control adjustable by a user for delivery of the sterile fluid at one or more rates selected by the user, the one or more rates being within the range of 30 ml/min to 1000 ml/min, wherein the desired volume ranges from 100 ml to 5000 ml." Claim 4 is therefore not obvious over the combination of Maddock, Wheeldon, Ruiz, and Savage.

Objective Evidence of Nonobviousness

Enclosed herein are two declarations under 37 CFR 1.132 that are being submitted as objective evidence of nonobviousness. The first declaration is from Dr. Mark L. Jewell, a plastic surgeon with over 30 years of experience in the field of aesthetic medical procedures, including Ultrasonic Assisted Lipoplasty (UAL) and breast augmentation procedures. As noted in Dr. Jewell's Declaration, the precision fluid management system (PFMS), manufactured by the assignee of the present application Sound Surgical Technologies LLC ("Sound Surgical") and

which embodies the claimed invention, met a long felt need in the medical profession. The second declaration is from Daniel S. Goldberger, inventor of more than 50 medical device patents, an accomplished businessman in medical technology companies and currently the CEO of Sound Surgical. Mr. Goldberger's reports that the only devices that he is aware of that are currently available for rapidly and precisely delivering fluid in aesthetic medical procedures are copies of the PFMS included within this patent application.

Dr. Jewell's Declaration establishes that prior to the introduction of the VASER® system[1] with PFMS (which incorporates the features of the claimed invention) there was a need for a device that could rapidly and precisely deliver fluids for aesthetic procedures. The devices that were available prior to the introduction of the PFMS did not provide the combination of precision and speed that was needed for procedures such as UAL and breast augmentation.

As noted by Dr. Jewell, aesthetic procedures require fluids to be delivered with both speed and precision. For example, knowing the amount of wetting solution used during infiltration in a UAL procedure is important to determine the amount of ultrasonic energy to be applied. Also, precisely monitoring the amount of wetting solution avoids the risk of introducing excessive amounts of local anesthetic into a patient. In breast augmentation procedures, a surgeon must be able to precisely measure the amount of fluid delivered to breast sizers in order to be able to select the appropriate permanent breast implant. The rapid delivery of fluid is also important to reduce the amount of time an aesthetic procedure takes, resulting in a reduction in the likelihood of patient side effects such as infection. Rapid delivery of fluid also reduces the duration of the procedure and the likelihood of surgeon fatigue during the procedure.

Dr. Jewell also notes that the devices available prior to the release of the PFMS did not satisfy the need for speed and precision. The two common ways for delivering fluid, namely a pressure collar or syringes, did not provide the combination of speed and accuracy needed for aesthetic procedures.

Dr. Jewell goes on to describe that Sound Surgical's PFMS met the unfelt need by providing a device that for the first time enabled aesthetic surgeons to deliver fluids both quickly

[1] The "Vaser® system" is the device manufactured and sold by Sound Surgical system for performing ultrasonic assisted lypoplasty including both fragmentation and aspiration of tissue. Later, applicant manufactured and sold the PFMS with the Vaser® system so that physicians performing aesthetic surgery could quickly and accurately deliver fluid.

and accurately in aesthetic medical procedures. Dr. Jewell notes that Sound Surgical's PFMS is the first system that he is aware of that was available to the market that precisely monitored rapid fluid flow for aesthetic medical procedures. In fact, in 2007 Dr. Jewell noted in literature:

> *The Sound Surgical VASER device can measure volume of wetting solution infused to the cc in a given area. This overcame the imprecise manner that was formerly used of a pressure bag of wetting solution and to look for "tissue firmness" clinically.* It was safe to infuse wetting solution approximately a range of 1.5–2 times the anticipated tissue aspirate from a given area.

Innovations in Plastic and Aesthetic Surgery, edited by Marita Eisenmann-Klein, Constance Neuhann-Lorenz, ch. 55, §55.11, Wetting Solution Measurements, p. 446 (emphasis added). Dr. Jewell further states in his Declaration that the only other systems that he is aware of that provide for rapidly and precisely delivering fluid and aesthetic medical procedures are copies of Sound Surgical's VASER system with the PFMS.

Indeed, the Declaration of Daniel S. Goldberger supports Dr. Jewell's statements that devices that are currently available, for rapidly and precisely delivering fluid to aesthetic medical procedures, are copies of Sound Surgical's VASER system with the PFMS (which as noted above incorporates the features of the claimed invention). Mr. Goldberger knows of two products that are copies of Sound Surgical's VASER system with the PFMS. Mr. Goldberger has not only reviewed literature that described the two products but has also observed the actual products. As noted in Mr. Goldberger's Declaration, the two products are EZ Pump™ by Mentor and Tumescent Measuring Device by M.D. Resources.

Applicant submits that the two declarations of Dr. Jewell and Mr. Goldberger provide objective evidence that the claimed invention is not obvious. The claimed invention solved a long felt need in the medical profession. Furthermore, even today the only available products for satisfying that need are copies of the claimed invention.

CONCLUSION

This document responds to the Final Office Action mailed on August 19, 2010.[2] For the reasons set forth herein, applicant respectfully submits that this application is in condition for allowance.

No additional fees are believed due with this response. However, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment with respect to this patent application to deposit account number 13-2725.

Respectfully submitted,

Date: February 22, 2011

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[2] Still, the office action may contain arguments and rejections that are not directly addressed by this document because they are rendered moot in light of the preceding arguments in favor of patentability. Hence, failure of this document to directly address an argument raised in the office action should not be taken as an indication that the Applicant believes the argument has merit. Additionally, failure to address statements/comments made in the office action does not mean that the Applicant acquiesces to such statements or comments. Furthermore, the claims of the present application may include other elements, not discussed in this document, which are not shown, taught, or otherwise suggested by the art of record. Accordingly, the preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability.